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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,331	12/12/2001	Michael T. Milbocker	PRAXIS-5	9980
7590	05/17/2006		EXAMINER	
PROMETHEAN SURGICAL DYNAMICS LLC			FUBARA, BLESSING M	
3 GILL ST.			ART UNIT	PAPER NUMBER
SUITE G				
WOBURN, MA 01810			1618	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/020,331	MILBOCKER, MICHAEL T.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 February 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14, 17-30 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14, 17-30 and 40-48 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/6/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

Examiner acknowledges receipt of amendment, remarks, and rule 1.32 declaration, filed 2/23/06 and IDS filed 3/06/06. Claims 1-14, 17-30 and 40-48 are pending.

The rejection is made non-final in order to address the content of PO:EO disclosed in Muller that was not addressed in the previous action.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. (US 5,624,972).

Muller discloses polymeric compositions comprising isocyanate-terminated polymers and a polyisocyanate composition (column 3, lines 8-16) and the composition comprises at least two polyisocyanate compositions, one is low in NCO polyisocyanate and the other is high NCO polyisocyanate (abstract). Toluene diisocyanate (claim 6) and isophorone diisocyanate (column 6, line 45) are examples of polyisocyanates. The functionality of the polyisocyanate terminated polyol is between 2 and 8 with an excess of isocyanate composition (column 3, lines 8-16).

Additionally, Muller discloses that the composition comprises at least one other free polyisocyanate composition (See column 6, lines 38-62). These polymeric compositions contain PO/EO units; in the random copolymer, the oxyethylene content is from 10-80% and 2-30% for

block copolymers (column 4, line 67 to column 5 line 5; column 7, line 64 to column 8 line 25); 80/20 EO/PO and 25/75 PO/EO are also used (column 9, lines 46, 47). Muller meets the limitations of claims 1-3 and 8.

***Response to Arguments***

Applicant argues that the EO content is 2-30% in Muller while it is 70% in the claimed invention and that there is a limited range of PO:EO ratios that are suitable for use in hydrogels as tissue adhesives. That applicant's experimentation of the EO:PO ratios in the region of from below 10% to about 50% PO shows a 50% PO polymer to be unsuitable and a 25% PO available commercially was found to be suitable, that while an upper limit of 30% was estimated for the PO in the examined claims, there is no evidence in Muller for a critical PO limit in Muller.

3. Applicant's arguments filed 2/23/06 have been fully considered but they are not persuasive.

It is noted that Muller discloses a range of PO:EO polymers. For example, random copolymer having the oxyethylene content of from 10-80% and 2-30% for block copolymers (column 4, line 67 to column 5 line 5; column 7, line 64 to column 8 line 25) is disclosed; also, 80/20 EO/PO and 25/75 PO/EO are also used as disclosed in column 9, lines 46, 47.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-7, 9-14, 17-30 and 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US 5,624,972).

Muller provides polymeric compositions comprising isocyanate-terminated polymers and a polyisocyanate composition as is discussed above. Future intended use carries no patentable weight in a composition claim; and if the instant composition is applicable as a tissue adhesive, the composition of Muller should also be applicable as a tissue adhesive since Muller discloses polyol and polyisocyanate. Specifically, the random copolymer having 10-80% EO content (column 4, line 67 to column 5 line 1) suggests a PO content of about 20-90%. Thus while Muller does not specifically disclose the percent propylene oxide recited in claim 4, there is a suggestion for a broader range of 20-80% that overlaps the 10% at the lower end and encloses the 30% at the upper end.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Muller to device compositions comprising one or more polyols terminated with a polyisocyanate and free polyisocyanate. One having ordinary skill in the art would have been motivated to use the desired amounts of PO and EO as suggested by Muller that would be expected to result in a flexible polyisocyanate polymeric composition/adhesive having the inherent properties of the adhesive.

***Response to Arguments***

Applicant remarks that because Muller does not disclose the range in claim 4 and also in view of the declaration, the obviousness rejection cannot be maintained.

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6. Applicant's arguments filed 2/23/06 have been fully considered but they are not persuasive.

As disclosed above, Muller discloses and suggests PO:EO copolymer that has a ratio of from 20-80% in the PO. There is thus a suggestion for the range recited in claim 4 and the declaration has not taken into account all the combinations of PO:EO disclosed in the Muller reference, and it could also be said that the ranges used in the declaration also read on the ranges disclosed by the Muller reference.

*The Declaration: The declaration provided by applicants use PO:EO ratios that are within the disclosed ranges in the Muller reference and therefore, the declaration is not persuasive.*

***Claim Rejections - 35 USC § 112***

***NEW MATTER***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-14, 17-30 and 40-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is New Matter rejection. The specification does not support a recitation of a hydrogel composition that has at least 70% EO units in the PO:EO copolymer.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
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